

CLAIMS

- 1 A method of diagnosis of stroke or the possibility thereof in a subject suspected of suffering from stroke, which comprises determining the concentration of at least one polypeptide selected from Apo C-III, Serum Amyloid A, Apo C-I, Antithrombin III fragment and Apo A-I in a sample of body fluid taken from the subject.
- 2 A method according to claim 1, in which the polypeptide is differentially contained in the body fluid of stroke-affected subjects and non-stroke-affected subjects, and the method includes determining whether the concentration of polypeptide in the sample is consistent with a diagnosis of stroke.
- 3 A method according to claim 1 or 2, in which an antibody to the polypeptide is used in the determination of the concentration.
- 4 A method according to any of Claims 1 to 3, in which the body fluid is cerebrospinal fluid, plasma, serum, blood, tears or urine.
- 5 A method according to any of Claims 1 to 4, in which the determination of the concentration of the polypeptide is used to determine whether a diagnosed stroke is of the ischaemic or haemorrhagic type.
- 6 A method according to any of Claims 1 to 5, which comprises subjecting a sample of body fluid taken from the subject to mass spectrometry, thereby to determine a test amount of the polypeptide in the sample, wherein the polypeptide is differentially contained in the body fluid of stroke-affected subjects and non-stroke-affected subjects; and determining whether the test amount is consistent with a diagnosis of stroke.

7 A method according to any of Claims 1 to 6, in which the polypeptide is present in the body fluid of stroke-affected subjects and not present in the body fluid of non-stroke-affected subjects, whereby the presence of the polypeptide in a body fluid sample is indicative of stroke.

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8 A method according to any of Claims 1 to 6, in which the polypeptide is not present in the body fluid of stroke-affected subjects and present in the body fluid of non-stroke-affected subjects, whereby the non-presence of the polypeptide in a body fluid sample is indicative of stroke.

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9 A method according to any of Claims 6 to 8, in which the mass spectrometry is laser desorption/ionization mass spectrometry.

10 A method according to any of Claims 6 to 9, in which the sample is adsorbed
15 on a probe having an immobilised metal affinity capture (IMAC), hydrophobic, strong anionic or weak cationic exchange surface capable of binding the polypeptide.

11 A method according to any of Claims 6 to 10, in which the polypeptide is determined by surface-enhanced laser desorption/ionisation (SELDI) and time of
20 flight mass spectrometry (TOF-MS).

12 A method according to any of Claims 1 to 11, in which a plurality of peptides is determined in the sample.

25 13 Use of a polypeptide selected from Apo C-III, Serum Amyloid A, Apo C-I, Antithrombin III fragment and Apo A-I, or a combination of such polypeptides, for diagnostic, prognostic and therapeutic applications relating to stroke.

14 Use according to Claim 13, in which the polypeptide is differentially
30 contained in a body fluid of stroke-affected subjects and non-stroke-affected subjects.

15 Use for diagnostic, prognostic and therapeutic applications, relating to stroke, of a material which recognizes, binds to or has affinity for a polypeptide selected from Apo C-III, Serum Amyloid A, Apo C-I, Antithrombin III fragment and Apo A-I.

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16 Use according to Claim 15 of a combination of materials, each of which recognizes, binds to or has affinity for a polypeptide selected from Apo C-III, Serum Amyloid A, Apo C-I, Antithrombin III fragment and Apo A-I.

10 17 Use according to Claim 15 or 16, in which the or each material is an antibody or antibody chip.

18 Use according to Claim 17, in which the material is an antibody to Apo C-III.

15 19 Use according to Claim 17, in which the material is an antibody to Serum Amyloid A.

20 Use according to Claim 17, in which the material is an antibody to Apo C-I.

20 21 Use according to Claim 17, in which the material is an antibody to Antithrombin III fragment.

22 Use according to Claim 17, in which the material is an antibody to Apo A-I.

25 23 An assay device for use in the diagnosis of stroke, which comprises a solid substrate having a location containing a material which recognizes, binds to or has affinity for a polypeptide selected from Apo C-III, Serum Amyloid A, Apo C-I, Antithrombin III fragment and Apo A-I.

24 An assay device according to Claim 23, in which the solid substrate has a plurality of locations each respectively containing a material which recognizes, binds to or has affinity for a polypeptide selected from Apo C-III, Serum Amyloid A, Apo C-I, Antithrombin III fragment and Apo A-I.

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25 An assay device according to Claim 23 or 24, in which the material is an antibody or antibody chip.

26 An assay device according to Claim 25, which has a unique addressable 10 location for each antibody, thereby to permit an assay readout for each individual polypeptide or for any combination of polypeptides.

27 An assay device according to any of Claims 23 to 26, including an antibody to Apo C-III.

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28 An assay device according to any of Claims 23 to 26, including an antibody to Serum Amyloid A.

29 An assay device according to any of Claims 23 to 26, including an antibody to 20 Apo C-I.

30 An assay device according to any of Claims 23 to 26, including an antibody to Antithrombin III.

25 31 An assay device according to any of Claims 23 to 26, including an antibody to Apo A-I.

32 A kit for use in diagnosis of stroke, comprising a probe for receiving a sample of body fluid, and for placement in a mass spectrometer, thereby to determine a test 30 amount of a polypeptide in the sample, wherein the polypeptide is selected from Apo

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C-III, Serum Amyloid A, Apo C-I, Antithrombin III fragment and Apo A-I, or any combination thereof.

33 A kit according to Claim 32, in which the probe contains an adsorbent for
5 adsorption of the polypeptide.

34 A kit according to Claim 33, further comprising a washing solution for removal of unbound or weakly bound materials from the probe.

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